

Remarks/Arguments

A. Status of the Claims

Claims 10 – 18 and 25 – 31 were elected by Applicants in response to the Requirement for Restriction dated November 14, 2005 and are pending. Claims 1 – 9 and 19 – 24 are withdrawn. Claims 10 – 18 and 25 – 30 are rejected. Claims 10 – 14, 18, 25, and 27 – 30 are currently amended. Claim 31 is cancelled.

B. Personal Interview

Applicants kindly thank the Examiner for granting the interview with the undersigned and applicants Vinay Sakhrahi and Charles Tomasino held on August 23, 2006. During the interview, the undersigned stated that the purpose of the meeting was primarily a technical discussion of the applicants' invention. The undersigned also briefly discussed the Examiner's rejections and stated that the Examiner had not met the *prima facie* case for either obviousness or anticipation. The undersigned also stated that the Examiner's view that "any pressure" as stated in the Williams patent in reference to the operating conditions of the plasma effectively includes all pressures from zero to infinity, and that "synthetic oils" as stated in the Williams patent includes all possible synthetic oils not just the class of oils discussed in the specification and presented in the claims, effectively stifles all further development in this art. Applicants believe that such a broad interpretation is unreasonable and would be contrary to the goals of the U.S. Patent and Trademark Office.

Applicants then demonstrated the performance of commercially available lubricated syringes and syringes treated according to Example 2 of the Williams patent and the applicants' invention. First, the Examiner was presented with a commercially available syringe coated with a silicone lubricant and no plasma treatment. The Examiner operated the syringe and found that a high initial force was required to begin movement of the stopper (break free force), and then the stopper movement exhibited stick-slip phenomenon where the stopper would alternately stick then suddenly move. Applicants explained that the stick-slip movement was due to migration of the lubricant from the stopper-barrel interface.

Next, the Examiner was presented with a syringe treated according to the teachings of the Williams patent. The Examiner operated the syringe and found that the stopper was difficult to move initially (high break free force) and required a very large force to sustain movement of the stopper. The Examiner was then presented with a syringe coated with a perfluoropolyether lubricant that was not exposed to any plasma. The Examiner found that this syringe operated similarly to the commercially available silicone lubricated syringe discussed above.

The Examiner was then presented with a syringe treated according to the applicants' invention (perfluoropolyether lubricant exposed to an atmospheric pressure plasma). When the Examiner operated this syringe, he found the stopper required markedly less force to initiate movement (very low break free force), and that movement could be sustained with a minimal force, unlike the syringe treated according to the Williams patent. Finally, the Examiner was presented with a syringe coated with a perfluoropolyether lubricant and exposed to vacuum plasma. The Examiner found that the stopper could not be moved in the syringe barrel. Applicants explained that the vacuum plasma contains a much higher level of energy than the atmospheric plasma, and the lower energy of the atmospheric plasma is necessary to achieve the proper cross-linking of the perfluoropolyether lubricant of the applicants' invention.

The Examiner then agreed that the applicants have an invention and the product produced by the applicants' invention is different from that produced by the teachings of the Williams patent. The Examiner further stated that his obviousness rejection can be overcome by the results of this demonstration, and that his anticipation rejection can be overcome by presenting the unexpected results of the applicants' experimentation. The examiner concluded by stating that the applicants should amend the claims to be commensurate in scope to the experimentation.

C. The Claims Are Not Anticipated by Williams et al. Pursuant to 35 U.S.C 102(b)

The Examiner rejected claims 10 – 12, 14 – 18, 25 – 28, and 30 as anticipated by Williams et al. under 35 U.S.C. 102(b).

To constitute an anticipatory reference, the prior art must contain an enabling disclosure. *Chester v. Miller*, 906 F.2d at 1576 n.2, 15 U.S.P.Q.2d at 1336 n.2 (Fed. Cir. 1990); *see also Titanium Metals Corp. of America v. Banner*, 778 F.2d at 781, 227 U.S.P.Q. at 778 (Fed. Cir. 1985); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1578, 18

U.S.P.Q.2d 1001, 1011 (Fed. Cir. 1991); *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 54 U.S.P.Q.2d 1299 (Fed. Cir. 2000) citing *In re Donohue*, 766 F.2d 531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). A reference contains an enabling disclosure if a person of ordinary skill could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself, and thereby the public, in possession of the invention. *In re Donohue*, 766 F.2d 531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985); *In re Sheppard*, 339 F.2d 238, 242, 144 U.S.P.Q. 42, 45 (C.C.P.A. 1964). See *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 54 U.S.P.Q.2d 1299 (Fed. Cir. 2000), for an example of the court vacating a summary judgment of invalidity because the district court wrongly constructed the hypothetical person of ordinary skill in the art.

The requirement that an enabling disclosure place the public in possession of the invention is consistent with the fundamental purpose of the patent law to promote the sciences and useful arts through the disclosure of useful knowledge. *Akzo N.V. v. U. S. Int'l Trade Comm'n*, 808 F.2d at 1479, 1 U.S.P.Q.2d at 1245 (stating that when a prior art reference would enable the worker of ordinary skill to practice the invention, it is deemed to have placed the invention in the possession of the public as well), cert. denied, 482 U.S. 909 (1987). When the reference relied on expressly anticipates all of the elements of the claimed invention, the reference is presumed operable. As a consequence, to remove a reference on grounds that it does not enable what it discloses, an applicant must prove that no operable technique existed to produce the product or perform the process disclosed by the reference. See *In re Sasse*, 629 F.2d 675, 681, 207 U.S.P.Q. 107, 111 (C.C.P.A. 1980).

On this point, applicants refer the Examiner to the declaration submitted by one of the inventors of the subject invention included with this paper as Attachment 1. This declaration presents the results of laboratory experiments comparing the process defined by Williams (polydimethylsiloxane lubricant treated with vacuum plasma) and the applicants' invention (perfluoropolyether lubricant treated with an atmospheric pressure plasma). Results are also presented using the perfluoropolyether lubricant without any plasma treatment and with vacuum plasma treatment. Figure 1 of the declaration shows that a very high force is needed to even move the stopper in the syringe barrel and that the limit of the force measuring apparatus is eventually reached. Figure 2 of the declaration shows that only a very minimal force is needed to move the stopper in the syringe treated according to the applicants' invention and that the

force remains consistently low throughout the range of travel. Figure 2 also shows that treating the perfluoropolyether lubricant with a vacuum plasma gives results similar to the Williams process in that the force necessary to move the stopper continually increases until the limit of the force measuring apparatus is reached. Finally, Figure 2 shows that a syringe barrel lubricated with a perfluoropolyether compound and exposed to no plasma exhibits extreme stick-slip phenomenon, which is not demonstrated by the atmospheric plasma treated perfluoropolyether lubricant.

Thus, this experimentation shows that no operable technique existed by means of the Williams patent to produce the product of applicants' invention. Williams, therefore, does not provide an enabling disclosure. Applicants submit that the present claims, as amended, are allowable under 35 U.S.C. 102(b) and respectfully request the Examiner to forward this application to issuance at an early date.

D. The Claims Are Not Obvious Over Williams et al. Pursuant to 35 U.S.C. 103(a)

The Examiner rejected claims 10 – 12, 14 – 18, 25 – 28, and 30 as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Williams.

To establish a prima facie case of obviousness requires, first, that there be some suggestion or motivation, either in the reference itself, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. As previously discussed in the applicants' response to the First Office Action, the applicants contend that the Examiner did not establish a prima facie case of obviousness. Applicants continue to maintain that a prima facie case has not been established and incorporate by reference their arguments from their response to the First Office Action.

The Examiner pointed out in the Final Office Action that “[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claim in a product-by-process claim, the burden is on the applicant to present evidence from which the examiner could reasonably conclude that the claimed product differs in kind from those of the prior art” (citations omitted). According to MPEP § 716.02, unexpected results of differences between the claimed invention and the prior art are evidence of nonobviousness.

Further, “[e]vidence of unobvious or advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness.” MPEP § 716.02(a). Additionally, “[e]vidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims.” MPEP § 716.02(b). In response, applicants direct the Examiner to the experimentation results presented in the declaration contained in Attachment 1 to this paper.

This declaration presents the results of laboratory experiments comparing the process defined by Williams (polydimethylsiloxane lubricant treated with vacuum plasma) and the applicants’ invention (perfluoropolyether lubricant treated with an atmospheric pressure plasma). Results are also presented using the perfluoropolyether lubricant without any plasma treatment and with vacuum plasma treatment. Figure 1 of the declaration shows that a very high force is needed to even move the stopper in the syringe barrel and that the limit of the force measuring apparatus is eventually reached. Figure 2 of the declaration shows that only a very minimal force is needed to move the stopper in the syringe treated according to the applicants’ invention and that the force remains consistently low throughout the range of travel. Figure 2 also shows that treating the perfluoropolyether lubricant with a vacuum plasma gives results similar to the Williams process in that the force necessary to move the stopper continually increases until the limit of the force measuring apparatus is reached. Finally, Figure 2 shows that a syringe barrel lubricated with a perfluoropolyether compound and exposed to no plasma exhibits extreme stick-slip phenomenon, which is not demonstrated by the atmospheric plasma treated perfluoropolyether lubricant.

If, as asserted by the Examiner, the applicants’ claims are obvious over Williams, the results of the experimentation should have shown only mild differences in the force necessary to move the stoppers in the syringe barrel for the two methods. On the contrary, the results show the unexpected result that the applicants’ process is far superior to the Williams process in the shared property of maintaining lubricity between surfaces in contact with one another. Thus, this experimentation shows that the applicants’ invention is nonobvious over Williams. Applicants submit that the present claims, as amended, are allowable under 35 U.S.C. 103(a) and respectfully request the Examiner to forward this application to issuance at an early date.

E. Rejection of Claims as Unpatentable Over Williams in View of Lubrecht

The Examiner rejected claims 13 and 29 as unpatentable over Williams in view of Lubrecht. According to the Examiner, Williams teaches all of the limitations of claims 13 and 29 except for the use of a fluorochemical, perfluoropolyether, or functionalized perfluoropolyether compound as the lubricant, and Lubrecht teaches the use of a fluorine-substituted silicone.

Applicants, in their response to the first Office Action, amended the claims to remove all reference to silicone compounds to avoid reading upon the silicone compounds claimed by Williams. In the experimentation discussed in the declaration contained in Attachment 1 to this paper, applicants compared their invention using perfluoropolyether compounds to Williams and found unexpected results as described above. Accordingly, applicants have amended claims 13 and 29 to remove the reference to fluorochemical compounds. In addition, claims 10 – 12, 14, 18, 25 – 28, and 30 were amended to maintain consistency with amended claims 13 and 29. These claims now reference only perfluoropolyether compounds and are commensurate in scope to the experimentation described in the attached declaration.

Applicants contend that the amended claims are now in condition for allowance and respectfully request the Examiner to forward this application to issuance at an early date.

F. Conclusion

In view of the foregoing, the claims are now in form for allowance, and such action is hereby solicited. If any small point remains in issue which the Examiner feels may be best resolved through a telephone interview, he is kindly requested to contact the undersigned at the telephone number listed below.

All objections and rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and a Notice to that effect is earnestly solicited.

Respectfully Submitted,

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ATTACHEMENT 1

DECLARATION OF VINAY G. SAKHRANI